UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PRODUCTS, L.P., PHARMA MAR, S.A.,	**CIVIL ACTION NUMBER:**
	3:20-cv-09369-ZNQ-LHG
Plaintiffs,	
	***MARKMAN* HEARING**
v.	
	VIA REMOTE ZOOM
EVENUS PHARMACEUTICALS LABORATORIES, INC., JIANGSO HENGRUI PHARMACEUTICALS COMPANY, LTD., NATCO PHARMA LTD SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMACEUTICAL INDUSTRIES INC., FRESENIUS KABI USA, LLC,	**VIDEOCONFERENCE**
	REDACTED TRANSCRIPT
Defendants.	

Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608
January 4, 2022
Commencing at 11:00 a.m.

B E F O R E: **THE HONORABLE ZAHID N. QURAISHI, UNITED STATES DISTRICT JUDGE**

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(PROCEEDINGS held via Zoom videoconference before The Honorable Zahid N. Quraishi, United States District Judge, on January 4, 2020, at 11:00 a.m.)

THE COURT: Good morning, everybody. We're on the record. Janssen Products v. eVenus, docket number 20-9369. I know we're on the record and we're starting on time, so that's always nice. One of the benefits of Zoom. I've got a few housekeeping matters that I want to briefly chat about, but let me get appearances first from plaintiff and then defendants and then we'll go from there.

MR. LIZZA: Good morning, Your Honor. Pleasure to appear before you for the first time. Charlie Lizza and Bill Baton from the Saul Ewing firm on behalf of Janssen and Pharma Mar. And my co-counsel will introduce themselves as well.

THE COURT: Good to see you, guys, Mr. Lizza and Mr. Baton.

MS. ROYZMAN: Your Honor, good morning and happy New Year. Irena Royzman from Kramer Levin representing Janssen and Pharma Mar. And with me is Christine Willgoos, also of Kramer Levin, and Daniel Williams, also Kramer Levin.

THE COURT: Good morning and happy New Year to you guys as well.

MS. ROYZMAN: We also have two client representatives on the conference, Clara Jimenez, litigation counsel at Johnson & Johnson, as well as William McGowan, counsel at

Johnson & Johnson.

THE COURT: Great. Good morning.

Who's going to be speaking on behalf of the plaintiff today, or is it multiple people?

MS. ROYZMAN: It will be two people, Your Honor. It'll be myself and it'll be Dan Williams, an associate at the firm.

THE COURT: Okay. Great. Good morning to everybody on that side.

Let me hear from defense.

MR. MILLER: Good morning, Your Honor. Gregory Miller, Rivkin Radler, on behalf of the Sun Natco defendants. And with me today from the Knobbe Martens firm we have William Adams and Karen Cassidy, and Mr. Adams will be taking the lead for us today.

THE COURT: Good morning, to all of you.

MR. RICHTER: Good morning, Your Honor. James Richter of Midlige Richter on behalf of the eVenus, Fresenius, and Hengrui defendants, and with me on the call today is Ivan Poullaos from Winston & Strawn.

MR. POULLAOS: Good morning, Your Honor.

THE COURT: Good morning. Good morning, Mr. Poullaos.

Mr. Richter, who's speaking on your end?

MR. RICHTER: So, Your Honor, we don't anticipate any

-- of us speaking today.

THE COURT: Okay. That makes it even easier.

So let me ask you this then. Let me ask this from the plaintiffs' side first. I just want to get a sense of what's being done today. I got the briefs. I've got the demonstrative, the deck or the slides, and I've reviewed those. What do you anticipate presenting today, or are you just going over the slides?

MS. ROYZMAN: I think, Your Honor, it's -- our thought was it's whatever is helpful to you, but we are prepared to present our technology tutorial as well as to give more substance and body to the slides that Your Honor has reviewed.

THE COURT: Okay. That would be helpful. There's no witnesses or anything like that from your end, correct?

MS. ROYZMAN: No. No, there are not.

THE COURT: Mr. Adams, is that the same on your end?

MR. ADAMS: It is, Your Honor. I think what the parties did before this call was to meet, confer, and talk about sort of the presentation today to make sure we're all on the same page. We've done that. I think the parties agreed to a certain time limit and the order. And I think the idea is really to just add more body to what you have in front of you already.

THE COURT: That will be helpful for me.

What is that timing? Just so I have a sense of it, too. Ms. Royzman, from your end, how long are you anticipating? I don't have a clock so you have my time, but I'm just curious as to how much time you anticipate you're going to be today.

MS. ROYZMAN: Your Honor, I think for the tech tutorial as well as the claim construction analysis we anticipate 45-to-50 minutes. And then, of course, you know, time for Your Honor's questions during or after the presentation as well as any -- as well as any rebuttal. But what we had discussed with Mr. Adams and the Natco defendants is that plaintiffs, again subject to your preference, would go first and present their arguments.

THE COURT: I think that makes sense.

Mr. Adams, that's something that you guys have agreed to? Do you have a similar time frame, 45, 50 minutes on your end?

MR. ADAMS: We do, Your Honor. We did agree to that. I think the concept is plaintiffs go first with their tech tutorial as well as their argument. We will respond with our presentation. I think the time frame will be about the same, 45-to-50 minutes, something like that. And then, you know, obviously subject to your questions, Your Honor, if you have questions during the presentation you might go over at the end. However you prefer to do it we're certainly able to do

that.

THE COURT: Okay. I'll tell you from my perspective what I will likely do, and so I might as well give you a heads-up now, is I think after both your presentations, unless something strikes me during the presentation where I need to interrupt you with a question, what I'm likely to do is to temporarily adjourn for about 30 minutes when both your presentations are complete. I'll want to get my thoughts together with my notes, and then I'm going to come back on and to the extent I have any additional questions, I'll pose them then. If I don't have any additional questions ^ , then I'll adjourn us for the day. Does that work for everybody? I'm going to break for about 30 minutes so I can collect my thoughts after both presentations and circle back to you. Does that work for you, Ms. Royzman?

MS. ROYZMAN: It does. We weren't planning to do rebuttal because we're going to go first.

THE COURT: I'll give you that opportunity as well then.

Let me ask you all this. Are you guys going to work through? I don't eat lunch, so I'm deferring to all of you on whether you plan to work through or do you need me to break so you all can, I don't know, grab a sandwich or whatever it is that you may want to do?

MR. ADAMS: I think in terms of my preference, Your

Honor, I'm certainly happy to work through. I think it makes a lot of sense in terms of efficiency and timing and for Your Honor's own timing. And so I think from our perspective going through as we agreed with what plaintiffs going through each side's preparation, and then like you said, if you take your adjournment and come back, I think that would probably be a good natural break for us to take anyway.

THE COURT: Ms. Royzman, does that work for your end? I'll give you all one. I just didn't know what the expectation was from counsel.

MS. ROYZMAN: I think a ten-minute break, something along those lines would be helpful.

THE COURT: Do you guys want it before your rebuttal? Where do you want me to do that? It's a little after 11:00, so I'm just trying to get a sense of do you want to let me know where you want to break, or do you want to break before you do a rebuttal and then I'll break at the end of that? You tell me.

MS. ROYZMAN: I think before the rebuttal would be very helpful.

THE COURT: Any objection there, Mr. Adams? I don't see why there would be.

MR. ADAMS: There's not, Your Honor.

THE COURT: I'll hear from the plaintiffs. I'll hear from defendants. We'll take a brief break, maybe ten minutes

or so, and, Ms. Royzman, you can tell me then how much you will need and that's fine. We'll take a break for everybody and then jump back on for rebuttal. And then I'll break again, but for a little bit longer, maybe 20, 30 minutes just so I can collect my thoughts. I think that makes sense.

What else? Anything more from the plaintiff before we start? You guys can walk me through this. No.

MS. ROYZMAN: No, thank you.

THE COURT: Mr. Adams, anything on your end?

MR. ADAMS: One comment. I think that plaintiffs are reserving time for rebuttal. We would ask the same thing in terms of the rebuttal. We at least get an opportunity to hear that and respond if there is a response. So we would ask for that as well.

THE COURT: Ms. Royzman, how long is this rebuttal that you're anticipating? You know what the arguments are going to be, so I'm just trying to get a sense from you. It's not like Mr. Adams is going to bring up something shocking here from his side. He's already briefed it.

MS. ROYZMAN: I think the rebuttal will be short, Your Honor. It depends on the argument, but I imagine it will be short.

THE COURT: Mr. Adams, I have no objection to hearing from you, but I'm not going to go back and forth. I'm not going to do surrebuttal and sur-replies and all the rest of

it. If you both want one opportunity for rebuttal, and Mr. Adams, if you want to briefly address it, I don't see any reason why I should prohibit that, but at some point we need to end. Does that work for everybody?

MR. ADAMS: It does, Your Honor. Thank you.

THE COURT: I don't have anything more. This is probably the most you're going to hear from me today. So I'm going to turn it over to.

I have the deck slides from both of you, but I was going to look at a hard copy. Are you going to be needing me to look at anything on the screen? I'm right now set up on a laptop. I don't have a dual monitor. I have a dual monitor on my left, but does it matter how I'm reviewing this, Ms. Royzman?

MS. ROYZMAN: I don't think it does. I was going to share the slides, so would that allow you to see them?

THE COURT: I'm on a single monitor, but I have the slides in hard copy. So if you refer to the slides by page, I can easily follow you. I have them literally right in front of me. Does that work for everybody? Only because I'm concerned that I'd have to reboot on to my desktop with two monitors for me to be able to see the documents, unless you want to test it out briefly.

MS. ROYZMAN: Let's test it out. I think we'll be okay, Your Honor.

THE COURT: Okay. I see all of you, but I don't see the document.

MS. ROYZMAN: Sorry, Your Honor.

THE COURT: That's all right. Let's just test it out now.

MS. ROYZMAN: Here we go.

THE COURT: I have no problem with you sharing the slides on the screen as well. I may take notes on my hard copy, but does that work for everybody? I can see everyone so I don't have any technical issues on my end.

MR. ADAMS: It works for defendants, Your Honor. I think what we'll try to do is to say slide numbers as we talk.

THE COURT: If you guys don't mind doing that, I'll be watching, but because I have a hard copy in front of me, I prefer to -- I'm old school. I like to handwrite on paper, so it will be useful if you can refer to the slides by page, and if somehow I lose you, I may ask you or interrupt you just to remind me of where we are. Okay?

MS. ROYZMAN: That sounds good, Your Honor.

So Dan Williams, an associate at the firm, is going to present our technology tutorial. So I will hand it over to Dan.

THE COURT: Thank you.

MR. WILLIAMS: Good morning, Your Honor.

THE COURT: Good morning, Mr. Williams.

MR. WILLIAMS: The patent before you, the '557 patent, covers pharmaceutical formulations of trabectedin. Trabectedin is also known as ET-743.

This case is about the defendants' generic copies of a drug named Yondelis®. Here we'll refer to Natco's generic version of Yondelis® as Natco's ANDA product. So if you look at slide 2. Yondelis® is a lifesaving cancer drug developed by Pharma Mar and Janssen that treats specific types of rare soft tissue cancer that were difficult to treat. In the decades prior to Yondelis® there were no promising new therapy options for the patients with these rare soft tissue cancers when conventional treatment options failed.

In 2015, the FDA approved Yondelis® and it has been marketed by Janssen in the United States ever since.

An essential aspect to bringing Yondelis® to the market on a commercial scale is the ability to store the product for long periods of time at refrigerated temperatures and without any major degradation of the product. It is the unique formulation for trabectedin that made it possible to commercialize Yondelis®, and it's that unique formulation for Yondelis®. That is what the '557 is all about.

If you look at slide 3, generally speaking, pharmaceutical products can be administered to patients in a variety of different ways. For example, drugs can be ingested orally. For example, they can be formulated as tablets or

capsules that can be swallowed. They can be formulated as a product that can be injected. They can be formulated as a topical product that can be applied to the surface of the skin, eyes, or ears, or they can be formulated as something that can be inhaled.

Yondelis® was formulated as a lyophilized injectable drug, which means that the formulation is freeze-dried into a dry cake for purposes of storage, and then it's later re-liquified just prior to using it to treat a patient.

If you turn to slide 4, please.

When we say "formulation," we're referring to the mixture of ingredients that make up the drug product. All drug formulations have an active ingredient. This is the active substance of the drug product and is often referred to as the active pharmaceutical ingredient or API of the drug product. It is the thing that causes the desired pharmaceutical effect in the patient. Most often drug products also have inactive ingredients, which are typically present to help deliver the active substance.

If you turn to slide 5, please.

Some drug products have just one active ingredient while others can have multiple active ingredients. It is very easy to tell how many active ingredients there are in a drug product. This can be readily determined by simply looking to the prescribing information or the packaging.

As you can see here, Yondelis®, on the far left, has one active ingredient and that is trabectedin. Other drugs can have more than one active ingredient, but again, the number of active ingredients can be clearly determined by just looking at the packaging. If you look in the middle, Biktarvy® has three active ingredients and on the right Symtuza® is a drug that has four active ingredients.

If you turn to slide 6, please.

As I mentioned, Yondelis® has one active substance; it is trabectedin. This is abundantly clear by simply looking to the product label or the prescribing information as you can see on the left.

If you turn to slide 7, please.

Yondelis® also has several inactive ingredients, which we've highlighted for you here on the slide.

Turn to slide 8, please.

Impurities are unwanted things that end up in the final product. As you can see on this slide, there are many different types of impurities. For example, there can be metal impurities from the manufacturing equipment used to make the drug. Other examples include impurities that arise from the preparation of the active ingredient or its degradation in the formulation. The bottom line is that all drug products inevitably contain some kind of impurity. It is completely expected.

If you can turn to slide 9, please.

The fact that all drugs contain some kind of impurities is a fact that is agreed by both sets of parties in this case. Here we have plaintiffs' Dr. Cory Berkland on the left as well as Natco's Executive Vice President of Research and Development, Dr. Pulla Reddy, on the right, testifying to that fact.

Unless you have any further questions, Your Honor, I'll pass the presentation over to my colleague, Ms. Irena Royzman.

THE COURT: You know what, maybe just one, Mr. Williams, and this just comes out of ignorance. When you talk about the packaging of the active ingredients, is that a requirement for a pharmaceutical packaging that the active ingredient is always identified on the package, or were you just showing me three examples in which that was done, including your drug?

MR. WILLIAMS: I believe it's required. I don't know that I can make a hard representation, but it's my understanding that that's what you have to do is put the active ingredient on the packaging. I think it might be a requirement by the FDA, but I'm not a hundred percent certain. But those three examples clearly show that the packaging lists the active ingredient. I believe that to be the case for all drugs on the market in the U.S.

THE COURT: Okay. Thank you.

MR. WILLIAMS: Thank you, Your Honor.

MS. ROYZMAN: Your Honor, and I second that. That is, -- those were just exemplary. That's always the case; the active is on the label and on the packaging. It has to be identified.

Okay. '557 patent. As Dan Williams described, the patent protects trabectedin formulations. Prior art formulations were unstable and had high levels of these undesired impurities, and the patented formulations stabilize the active ET-743 and reduce impurities. All the generic manufacturers involved in this case and in the related MSN case that's also pending before Your Honor copied the patented formulations exactly. They're very useful.

The summary of the invention for the patent says the present invention provides ET-743 compositions, which comprise ET-743, the active, and the disaccharide the -- an inactive ingredient. The patent explains that ET-743 formulations face the problem of relatively large amounts of impurities and these impurities are produced during the lyophilization process and during storage of the formulation. And the patent also explains that ET-701 is the main impurity.

Because of that, the patent sets forth a specific goal, and the specific object of this invention is to provide new stable formulations of ET-743. And the inventors discovered that use of certain inactive ingredients, certain

disaccharides as bulking agents can drastically reduce the formation of impurities and also allowed the product to be stored at refrigeration temperatures, as Dan Williams described.

Now, all the formulations that are exemplified and described in the patent are ET-743 formulations. And there are 22 of them and we have pulled them out for Your Honor. These are tables in the patent and we have highlighted in green all the examples of ET-743 formulations and these are the only formulations. And ET-743 is the active in all of them and the other ingredients are inactives.

One of the formulations on that list in table XVI is referred to ET-NF-G. That's the preferred form ET-743 formulations and described as such in the patent. And the composition is -- of that formulation is set forth and it matches exactly with that of Yondelis®, which is to your right on slide 16, Your Honor, and they are -- they are an exact -- they are an exact match.

On slide 17 the patent also explains that all of the ET-743 formulations, "embodiments of formulations according to this invention," this is text from the patent, have impurities, have potential impurities, and these include ET-701, ET-745 and other impurities.

So what's the claim construction issue with that background? So the -- this is a representative claim. There

are two independent claims, claim 1 and claim 22, and -- and the claim is to lyophilize the anti-tumor composition where it has an active and it has inactives and a certain beneficial effect: the reduction of ET-701 impurities. And the dispute is with respect to one term: a single active anti-tumor compound. So the dispute is with respect to the active of the composition. Only Natco has sought construction of this term. None of the other defendants have.

What are the parties' constructions?

THE COURT: I know you make that point, but it's not dispositive. Is your point behind that, hey, Judge, if there was any real argument here, all the defendants would support Natco's construction theory? Is that the point of that?

MS. ROYZMAN: That's one of the points, and -- but also, Your Honor, the term is just clear. And all the other defendants have the same to gain and this is -- and they are not comfortable making this argument and are not joining this argument that Natco is presenting here.

THE COURT: Ms. Royzman, just so I understand the plaintiffs' perspective on this, you have an alterative argument. You're not asking the Court to find that the claim term should be interpreted as single compound providing the anti-tumor activity of the composition. What you're saying is the plain and ordinary meaning should apply. That's the primary argument of the plaintiff, correct?

MS. ROYZMAN: Yes, Your Honor. So one of the disputes that has arisen is Natco says plain and ordinary meaning, you can't do that here because there's a dispute and the Court has to resolve the dispute. And we agree that the Court has to resolve the parties' dispute. But the Court can do that simply by rejecting Natco's position and adopting the plain and ordinary meaning of these very simple words: a single anti-tumor compound.

In the alternative, if the Court wants to construe the term, then we think it should be construed with its plain and ordinary meaning of an active. The single compound providing the active anti-tumor activity of the composition. There's no dispute between the parties as to single or compound. It all comes down to this active anti-tumor. And in our view, it's critical for active not to be written out and not to be taken out of the claim. And Natco's construction, as you'll see in a moment and as you've seen in our briefing, does that.

So the meaning of the claim term is clear. As we've already discussed, the other defendants didn't seek construction. MSN has already stipulated to infringement of the patent under the plain and ordinary meaning. Natco, in its paragraph IV certification, which is what started off this litigation, never challenged infringement, never asserted the type of claim construction that it is now. And it's -- now construction is driven by an incorrect non-infringement

theory.

Now, another dispute that's before the parties and that Natco raised in the -- in its reply brief is whether the Court can consider the accused device as part of its analysis. And the Federal Circuit precedent makes very clear -- and we had discussed this in our opening brief as well as our proposed reply brief that was filed last week -- but the case law makes very clear. And, in fact, the Federal Circuit has emphasized the importance of the context provided by an analysis of the accused device when ruling on claim construction and the problems presented by construing claims in a vacuum in the absence of such context. That just makes sense. The Court should be educated and have an understanding of the implications of its ruling.

And, again, this is *Typhoon* in 2011, the Federal Circuit says: It's not inappropriate for a court to consider the accused device when construing claim terms, for the purpose of claim construction is to resolve issues of infringement.

Natco has cited *Wilson Sporting Goods* to Your Honor. And as discussed in our proposed reply brief, and this was also in our opening brief, *Wilson Sporting Goods* stands for the proposition that context is extremely important. There, both sets of parties deprived the Court of any context. They failed to provide the court with any information about the

accused device, and the Federal Circuit said that doesn't work. The accused device provides meaningful context and the court shouldn't be deciding claim construction in a vacuum. So, in fact, what *Wilson Sporting Goods* -- what occurred in *Wilson Sporting Goods* and what it stands for is that the accused device is important in the analysis. It can't supply claim limitations, but it's very important for it to be considered. And the Federal Circuit remanded the case back to the District Court in order to consider claim construction in the context of the accused device.

[redacted]

[redacted]

The other fallacy of Natco's construction and why it's not even helpful to Natco in the first place is because [redacted] How do we know that? Just like Natco has to identify its active to FDA, it has to identify its impurities because FDA wants to know what the patient is getting. And that identification of impurities is [redacted]

[redacted]That's it. And so Natco is ultimately not helped by its incorrect claim construction position.

With respect to ET-701, Natco changed its position. It now concedes that [redacted] and it's the main impurity that's described in the '557 patent, is expressly excluded by the plain language of the claims from being an active anti-tumor compound. We agree. ET-701 makes very clear that the claims permit impurities and that impurities are not active anti-tumor compounds.

So Natco's, in sum, the construction's incorrect and premised on -- entirely premised on an incorrect theory. Natco now admits correctly that ET-701, an impurity, is not an active anti-tumor [redacted] And Natco filed a reply brief to -- to Your Honor arguing something different [redacted] And we had -- I think it's DI-181 -- submitted a proposed reply brief to Your Honor that again addresses this and [redacted]

So now the claim construction analysis, because I think

at this point Your Honor has the full background of what the parties are disputing and the context for the dispute.

So *Phillips*, Federal Circuit 2005 en banc, is an important Federal Circuit case that provides guidance to the courts as to how to conduct a claim construction analysis. And it provides a hierarchy of evidence that the court is to consider. And first it discusses the intrinsic evidence. There are three types. The claims, the specification, and the prosecution history. And *Phillips* says claims are the most important. That's where you look first because they set the metes and bounds of what, you know, of what's covered, what's protected. Then it's the specification and the construction that's in line with the specification is typically the correct construction.

Prosecution history is third in line because as the Federal Circuit explains, again in *Phillips*, it's the product, the back-and-forth with the patent office. So it doesn't have the same clarity as a final integrated document the way the claims and specification do.

And then below the intrinsic evidence is extrinsic evidence and the asterisks are there because it's far below. And understand extrinsic evidence, like dictionaries and articles and expert testimony, they can be helpful. They can provide background. Courts rely on them, but they have to be consistent with the intrinsic evidence and they can't

contradict it.

So let's start with the claims as *Phillips* instructs. So first we look to the claims. And the claims here are very instructive. The claims say this is a lyophilized anti-tumor composition that has a single active anti-tumor compound. How do we have an anti-tumor composition? It's because of the single active anti-tumor compound.

The claims also tell us what that compound is. It's ET-743. This is a lyophilized ET-743 formulation. And they also tell us that there's a benefit to this formulation, and that benefit is that there is less conversion of ET-743 into ET-701. It's less than 2% ET-770. So if you have a higher percentage, you're outside of this claim.

So what does the claim teach? ET-743 is the single active. ET-743 provides the activity of the composition. That's how we have an anti-tumor composition. And ET-701 is an impurity. It's clearly not an active anti-tumor compound.

The Federal Circuit in *Phillips* and in lots of cases has made clear when construing patent terms there's a heavy presumption that the language in the claim carries its ordinary and customary meaning, and we have very simple language here: a single anti-tumor compound.

Here is Dr. Berkland talking -- speaking to what that plain and ordinary meaning is, which comes off -- right off the claims and is consistent with the specification and

everything else. But he's saying that a person of ordinary skill in the art would understand the term to be the single compound providing the anti-tumor activity of the composition. It's the active.

So let's look at this specification, Your Honor. Again, following the hierarchy set forth by *Phillips*. So the specification, and *Phillips* points out, it's usually dispositive. It's the single best guide to the meaning of a disputed term. The construction should be consistent with the specification.

Again, the summary of the invention. Present invention is ET-743 compositions. They comprise inactive ET-743 and disaccharide, inactives. In summary, all examples are ET-743 formulations. There are 22 formulations that are exemplified. They have ET-743 as the only active. Patent makes very clear that ET-NF-G, one of those 22, is the preferred ET-743 formulation. There are no formulations with any other active that are exemplified. And all ET-743 formulations have potential impurities. The patent makes that clear, and ET-701 is the main one. And we looked at this evidence before, but slide 40 shows those 22 ET-743 formulations. Slide 41 focuses on ET-NF-G. And again, that's the preferred formulation and the formulation of Yondelis®. The patent makes very clear that formulation ET-NF-G is a preferred formulation; that text is right there.

Slide 43, immediately after saying that that formulation is preferred, the specification says embodiments of formulations, according to this invention, they were tested, and they all have impurities or potential impurities, including ET-701 and ET-745 and other impurities and they're below a certain level. So all the examples have potential impurities. That's what the patent teaches.

And again, ET-701, as we saw, is the main one. And again, a construction that encompasses the embodiments and stays true to the claim language will then be the correct construction. And that's the case here.

There's the prosecution history, Your Honor. Again, third in line, according to *Phillips*. So the prosecution history can limit the meaning of terms, but -- but the court must give claim language its presumptive ordinary meaning, limited solely by the patentee's clear and unmistakable disclaimer. And there's no disclaimer here, contrary to Natco's arguments of impurities, which all ET-743 formulations at some level have.

So before we get into the details of the prosecution history, at a high level what happens is there's a rejection over a prior art reference by the patent office. That reference is called Faircloth, and in response to that rejection applicants narrow their claims to specifically say that they will have a single active anti-tumor compound. And

the reason that that happened is they were being rejected over a formulation that, in the examiner's view, was a combination product. It had multiple actives so it looked like -- you think back to the technology tutorial that Dan Williams presented -- it looked like Symtuza® or Biktarvy®. It had multiple actives. And so in order to distinguish it, applicants explained that that's -- that's not what we're claiming. Here, our claims are directed to a single active anti-tumor compound where that active is ET-743. So it's not to these combo products.

So again, here's the rejection, and the patent office is saying that here we may have a formulation where you have two drugs in the same composition: kahalalide F and ET-743.

And in slide 49, in responding to that rejection, applicants say, well, we've amended our claims and now we say our compositions, they're not to multiple actives. They consist of a single active anti-tumor compound, which is ET-743. Therefore, our claims don't encompass combinations of kahalalide F and ET-743, if that's what Faircloth were to describe. And then they do it again. It's not two combinations of anti-tumor compounds.

Now, when you provide an amendment to the patent office, you have to provide support for your language. And that's exactly what applicants did. And looking at this support is very helpful because, again, it's instructive as to

both the meaning of the terms and what was actually given up versus what wasn't. And here, the amendment is supported and the language of the amendment is above by a paragraph that refers to the ratio of active substance to bulking agents. So applicants are providing support for the word "active." And we'll look at that in a second. But basically they're equating active with active versus inactive so the active ingredient.

In addition -- and this was just cut for brevity -- there's additional support about how drugs can be administered separately and so they don't have to be part of the same composition. That supported the construction. And then in addition, the examples of the application disclosed compositions, and we looked at all of them, there are 22, in which ET-743 is the only active anti-tumor compound.

Here is that paragraph. Again, it's equating active substance with active compound. This is the active of the composition and here is the further support for the claim amendment which makes -- because, again, applicants relied on all of the examples, and the patent makes clear that the examples have potential impurities, including ET-701 and ET-745. And so these are not being treated as actives in the prosecution history. To the contrary, applicants said these examples have a single active; it's ET-743. That's correct. These are impurities and they're permitted.

So here's the sum-up, but it's everything we've discussed. The claims were amended to recite a single active anti-tumor compound. That claim amendment was supported by a discussion of the active anti-tumor compound as the active substance, active ingredient of the composition. The claim amendment was supported with examples of the specification, all of which have ET-743 as the only active and all of which have impurities. ET-743 formulations with impurities were not disclaimed. Just the opposite. They were the support for the claim amendment. What did applicants give up? They gave up combo products along the lines of Symtuza® and Biktarvy®, products with combinations of actives, multiple drugs.

And again, the case law is very clear, any disclaimer is -- it's congruent with the scope of the surrender. You only surrender what you surrender, not more.

The extrinsic evidence here illustrates a couple of things. One, contrary to arguments being presented here and testimony cited, Natco knows what an active is. It -- it's a thing and it's a thing in every drug product and it has to be identified [redacted] Why did it do that? Because it's true. [redacted] Why did it do that? Because it's true.

[redacted] It's trabectedin. It's identified.

[redacted]

Now, Natco's construction is incorrect for a lot of reasons. It disregards the claim. It reads out "active." Can't do that. It injects ambiguity into the claims. It completely contradicts the specification. It disregards the disclosure. It ignores that all the embodiments have potential impurities. Natco's construction reads every embodiment of the invention out of every claim of the patent. It's leading the Court into error. It's not supported. It mischaracterizes the prosecution history.

So again, here's the claim. Claim is very clear. It requires an active anti-tumor compound. That active

anti-tumor compound is ET-743 and ET-701. An impurity is even expressly mentioned in the claims. Impurities by no means are disclaimed.

Contrary to the claims, Natco's construction attempts, through its possessing properties, to include potential impurities as active anti-tumor compounds when they're not. The claims made clear what the active is. They make clear what provides the activity of the composition, and impurities are expressly permitted.

The other fallacy here is that -- and again, as Dan Williams pointed out in the technology tutorial, impurities are inevitable. We're stuck with them. The FDA requires you to identify them, and that's because every single drug product on the market has impurities. Yondelis® and Natco's proposed generic ANDA product is no different. Impurities at some level are inevitable. And the courts understand that. And this case, *Allergan v. Teva*, this is a decision actually by Judge Bryson of the Federal Circuit, sitting by designation in the Eastern District of Texas. He actually relied in that case on the testimony of Dr. Berkland in connection with impurities, the same Dr. Berkland whose testimony we have cited here, including with respect to this undisputed issue.

In the real world -- and this is Judge Bryson -- in the real world, impurities are inevitable. Therefore -- and he explains, you know, you have trace amounts of impurities and

that any characterization of a pharmaceutical product in a patent claim must be assumed to include impurities, unless it's very clearly prohibited of all such impurities. And here the claims are the opposite. They recite -- they expressly recite the main impurity. They're not prohibited. Again, a useful decision from a Federal Circuit judge sitting by designation.

Here is a Federal Circuit opinion. Again, impurities normally associated with a component of a claim are implicitly adopted by the ordinary meaning of the components themselves. And in these cases -- and going back to slide 66 -- you know, defendants argue that somehow they have a non-infringement position based on impurities. In this particular case, the language was -- I think cyclosporin A is the only peptide and is the only peptide present. And so defendants, Teva there, tried to argue, well, so we have any impurities whatsoever, any peptide impurities. We're outside the [redacted] And Judge Bryson said no. And the Federal Circuit doesn't -- again recognizes that impurities are inevitable.

Okay. So a major error in Natco's construction, and again, because it's focused on alleged impurities, is to read out "active." That's what it does. It takes out the word "active." You no longer have an active and that's clear

error.

And *Vederi* is an example of a case where the court says by effectively reading out a claim term, I think substantially there, that the district court erred. It took out claim language.

Natco's construction also makes the claims less clear. This is not supposed to be an exercise -- or claim construction. It's not supposed to be an exercise that's unhelpful. It's supposed to resolve the parties' disputes, but it's not supposed to make the claims less clear or introduce ambiguities where there are none. And here, what properties and in what setting? Clearly, Natco is not focused on the setting of the lyophilized composition, the setting of the claim. It's not interested in that because it's relying on alleged impurities, which are not active.

This is Dr. Berkland noting that Natco's construction is confusing to a person of ordinary skill. And again, as this -- as this district has found in another case involving Sun, construction that only serves that vagueness isn't helpful and isn't the right way to go. So Natco's construction is contrary to the claims and injects ambiguity. It's wrong.

Natco also does violence to the specification. It disregards that all the examples are ET-743 formulations. It actually pretends that ET-743, ET-NF-G is not the preferred

ET-743 formulation when the patent says it is. And there are no formulations with any other active. And all ET-743 formulations have potential impurities. So -- and those are not actives. ET-701 is just the main one.

Again, every example is an ET-743 example. Every example has potential impurities.

The courts, in case after case, and we cited many on this point, normally do not interpret claim terms in a way that excludes disclosed examples in the specification. *Verizon* on slide 77 is one such example, but that's not what courts do. And here, Natco is asking the Court to read out every embodiment from every claim in the patent. It's asking, through its incorrect claim construction, for the patent to cover nothing, not to protect its ET-743 formulations, which all of the generics copied. It's asking for the Court to turn the patent into a nullity contrary to well-established law. This is clearer error. Natco ignores, again, the preferred ET-743 formulation. It's the commercial embodiment.

Claim interpretation that excludes a preferred embodiment, again, is rarely, if ever, correct. Here the problem is far worse than that, and the claim interpretation that excludes the inventor's device is rarely the correct interpretation. Again, that makes sense. The idea is not for a patent to be a complete nullity. Natco's construction is contrary to the specification. It's just flatly wrong.

As to the prosecution history, Natco claims that somehow impurities were -- were disclaimed. In ET-743 formulations, ET-745 and others are potential impurities, ET-701. They're not disclaimed. They were -- they were the support for -- for the amendment. Its -- its interpretation of the prosecution history is completely incorrect.

The claim amendment, here it is. They added a single anti-tumor compound. That anti-tumor compound is ET-743. They equate it. Active anti-tumor compound with active substance. It's -- it's a claim with a lyophilized anti-tumor composition that has one active, and it certainly allows impurities and, in fact, expressly recites the main one.

So again, Natco ignores the support, the support that tells us, that makes crystal, that the impurities in ET-743 formulations are not disclaimed.

Again, it relies on the examples as support, and all the examples have impurities.

The law is very clear. We -- courts must give claim language its presumptive full ordinary meaning, limited solely by the patentee's clear and unmistakable disclaimer. And there's no disclaimer of ET-743 lyophilized compositions with impurities. Those are the support for the claims.

Natco's construction is contrary to the prosecution history. Natco's construction is also incorrect. And it spends a lot of time, I think it submits many extrinsic

articles to Your Honor, and they have various studies about how to synthesize certain things and that they test ET-770 or ET-745 outside of the relevant context. The relevant context is ET-743 formulations. That's what the claims concern. The claims are ET-743 formulations. Those formulations, if ET-770 or ET-745 are [redacted] The patent tells us that. And so this barrage of references is really completely irrelevant. It doesn't support a construction -- the construction that Natco is advocating.

So Natco's construction has no support in any of the evidence, intrinsic or extrinsic, and really it leads the Court into error, and so we ask for the Court to resolve the dispute by rejecting Natco's construction and to adopt the plain and ordinary meaning of these very, very simple words. And to the extent the Court decides to or determines to construe the term, that the Court construe it in accordance with its ordinary meaning: the compound providing the anti-tumor activity of the composition.

Thank you, Your Honor.

THE COURT: Thank you, Ms. Royzman.

Mr. Adams, do you want to take a minute, or do we need a break? You tell me. How do you guys want to proceed? Do you guys want five or ten minutes before we switch to

defendants' position?

MR. ADAMS: Your Honor, unless you want to take a break, I'm fine going forward right now.

THE COURT: Okay. Let me reboot. Just give me a moment. I'm ready to proceed then if you guys don't want to take a break. We'll do what we said initially which is break after Mr. Adams presents.

MR. ADAMS: Your Honor, I can share my screen as well and walk through the slide deck. I know you have a hard copy there.

THE COURT: It was helpful, though, to have my notes written here while you referred to the slides even by page. Although, I will tell you, it's not hard to follow. If you don't mind sharing the screen, as Ms. Royzman did, and I'll view the screen and write in front of me.

MR. ADAMS: Okay.

MS. ROYZMAN: Good. You're set.

THE COURT: Yes, I can see it.

MR. ADAMS: Okay, great. Thank you, Your Honor.

So William Adams, again, from Knobbe Martens for the Sun and Natco defendants.

I really just want to start with a little background on Sun and Natco. Sun and Natco are both global pharmaceutical companies. They do both branded and generic side work across the globe.

Before I get into a tech tutorial, I know Your Honor has heard a lot about the technology, so I'll try to make this as efficient as possible and not retread a lot of the stuff you just heard, or obviously what you have in front of you in the briefing.

Before I jump into the tech tutorial, I really want to talk about sort of how we got here, and I titled this slide 3 in front of you Claim Construction Posture. You did hear a lot about this concept of Natco's ANDA product and Your Honor asked a regulatory question about what's supposed to be on the label. There's a lot of discussion in plaintiffs' briefing about Natco's product or their own product or the accused product or regulatory questions of the impurity levels and how much in identifying those and how do you do that and Dr. Reddy's testimony.

What is very apparent from the Federal Circuit case law is looking at accused product to try to read in a claim limitation, which is exactly what Natco -- which is exactly what plaintiffs are doing, is improper. The Federal Circuit said that over and over and over again. So that much we know is true. What you do is if you step back for a minute you think about how we got here because it's very apparent what plaintiffs are doing. Plaintiffs have walked through our accused product with it in hand and reread the claims. You just heard from plaintiffs' counsel this concept of this claim

term is very clear. And the plain meaning is the word on the page. But then they have an alternative plain meaning, so apparently there's two plain meanings. And that's where I think the confusion sets in. And if you step back for a minute and walk through how we got here, it starts to become very clear.

Earlier in this case defendants served their infringement and invalidity contentions. We put forth our non-infringement position. Plaintiffs responded to that, and that response is very apparent. Plaintiffs are reading this plain meaning of single active anti-tumor compound very differently than we are. And so the parties obviously went through with claim construction exchanges.

One of the things I want to point out, I know Magistrate Judge Goodman ruled on this allowed plaintiffs to later on amend their construction to add this new alternative proposal, but the local rules expressly require you to provide on the due day a simultaneous exchange of the plain meaning. We did that. We said here's our construction. Plaintiffs didn't do that. They said plain meaning. That's it. That's in violation of local rule 4.2.

But the point there, Your Honor, is this concept of them taking what we gave them, they take our construction, they take our evidence we gave them. For weeks they re-reviewed our non-infringement contentions. They met,

conferred with us, and out of that process popped out this new alternative plain meaning, which we talk about in our briefing and obviously now in our tutorial here. That construction cannot be correct. And that construction, more importantly, is based on this concept of looking at the accused product to really go back to the keyboard and rewrite the claim. So again, the Federal Circuit has told us over and over and over again that's improper.

And so what we really are left with under the Federal Circuit case level to my peril is there is a dispute here. That dispute needs to be resolved, and whether the ultimate construction is plain meaning means the word on the page, whether plain meaning means defendants' construction, it simply cannot be that the plain meaning is this alternative new construction that plaintiffs come up with.

So again, I'm going to try not to rehash a lot of the tutorial, but what I do want to do is talk a little about the background of these ecteinascidin or ET compounds. So the '557 was first filed from a priority filing in 2004. If we go back decades before that, what was well-known in the art, what were these ET compounds. In fact, they were discovered decades before, going back to 1969. And then six of those, at least six of those were isolated and identified by 1986. Again, the '557 patent was filed in 2004, so we're talking about a long time before that patent was filed. And what you

see in front of you is a discussion of that and really the concept of identifying these ET compounds was to understand what their utility was. Were they compounds that could be used for anticancer compounds. So back to 1986, scientists identified six of these. Of those were ET-743, which you've heard a lot about today, ET-745, and ET-770, among some other ones.

And so when you really -- when you go back and you look at the big picture from 1986 to 1990, scientists were working on these to see what their value was, their utility. And what the Rinehart publication tells us here -- again, this is prior art 15 years before the '557 patent was even filed -- that scientists by this time had identified and isolated, had tested and had understood that these compounds, including 743, 745 and 770, were potent anti-tumor agents. So that's -- you'll see this kind of go on and on as you walk through these slides. But what happened was scientists understood these a long time before we got to the patent. When you get to the patent, which I have in front of you, slide 6 here, the background of the patent starts talking about, again, these ET compounds and calling them a promising new class of anticancer agents.

So that's one concept I want to make sure we all understand. There's a lot -- they want to discuss about impurities, but what needs to be understood too is scientists

well before the filing of the '557 patent, the inventors of the '557 patent all understood that these ET compounds, including ET-743, ET-745, ET-770 and others were, in fact, active anti-tumor compounds. They all understood that. That was disclosed in the background of the patent.

Now the other concept I want to talk about in the patent is what was the invention here? What was the alleged invention? And so when you get to the '557 patent, by that time it really -- there's a lot in the art, and this is a very long prosecution history. But there's a lot in the prior art that talked about formulations or compositions of these ET compounds. And what was well-known then was there were stability issues with these and so they needed to be lyophilized. Lyophilized means really putting them in a powder form that can then be reconstituted and then injected. So with that framework, again, the sea of prior art that disclosed ET compounds alone and what's known as a mannitol or a monosaccharide, ET compounds with a second or third or additional anti-tumor compounds with a disaccharide in the composition, which we saw a moment ago in the Faircloth reference, those were all in the prior art.

So in view of that sea of prior art, that's when we get to what was eventually allowed in these claims. And these claims are, you know, narrowly drafted to cover specific lyophilization compositions.

What you see in front of you here on slide 8 is this, you know, lyophilized anti-tumor composition. It comprises several things. One of those is a single active anti-tumor compound. And then another one is a disaccharide. It lists specific disaccharides that can be used. And one of the points I want to make here to take away from these claims is these aren't -- these aren't method of treatment claims. These are composition claims. These are -- if you think for a minute, Your Honor, you're in your kitchen, you have a recipe. That's what these are. These are a formulation. You put some disaccharide in there. There's sucrose or lactose. You put a compound in there and that's the composition. There's also no specific quantity amount required of a single active anti-tumor compound. It simply needs to be one and only active anti-tumor compound. That's it. And so that's the framework of these claims. They aren't, again, method of treatment claims. There is no requirement or limitation about how much single active anti-tumor compound needs to be present here.

But then the prosecution history, while I'll talk about a little bit more detail today, you heard some already, what happened here is a long prosecution history that has to do with two parts here. One is the single active anti-tumor compound we've been talking about. As you know, in view of the Faircloth reference, kahalalide F plus ETF -- ET-743, the

patentees need to limit the construction or limit the claims to a single active anti-tumor compound.

The other part here that wasn't discussed much is this entire alleged invention -- and this is years of prosecution history -- was all about getting around the prior art using disaccharide with a specific amount of it -- with disaccharide to ensure that you had an impurity level of 701, which is a different limitation in the claim, needed to be below a certain amount. And that was required, again, to get these claims allowed. The patentees obviously understood that ET-701 was the impurity that they were concerned with, and that was written into the claims. You've heard a lot about active anti-tumor compound and ET-701 and impurities. ET-701 is a different limitation of the claim. Active anti-tumor compound is not discussing ET-701. It's -- the patentees dealt with that. The examiner understood that. That was in front of the examiner when the single active anti-tumor compound language was added to the claim. That's a different limitation. We aren't here today to talk about the limitation of 2% ET-701 after storage. That isn't under claim construction. Single active anti-tumor compound is what we're here to talk about today.

So that takes us to the disputed term, which defendants' construction, single compound possessing anti-tumor properties, is really the plain meaning. It's --

when you look at it in the context of the extrinsic record, it really has support -- the extrinsic record we cite to supports the concept of these anti-tumor compounds having these properties, which gives them this activity such that they are active anti-tumor compounds.

Now, when you look at plaintiffs' construction here, and, again, what we've heard numerous times is the term doesn't need to be construed because it has a plain meaning, but if you're going to construe it, the plain meaning in this long construction, the single compound providing the anti-tumor activity of the composition. It's a mouthful because it's a rewrite of the claim with a bunch of new words that have no support in the intrinsic record. And really this whole concept of this rewrite, as you've seen in the briefing, as you've heard already today, and as you'll see in our presentation is really focused on -- improperly focused on the accused product, used in the accused product it's called extrinsic evidence to rewrite the claim.

So here on slide 11 I'll just show you where the single active anti-tumor compound shows up. It's in both independent claims 1 and 2.

So let's start with the intrinsic record. The intrinsic record supports defendants' construction. We'll walk through the claim specification and prosecution history. Picking up here, it starts with the claims. The claims --

when we start thinking about single active anti-tumor compound, let's talk about single for a minute. Single means one; one and only one. It doesn't mean additional one. And it seems like at this stage plaintiffs appear to agree, as they stated in their opening brief, single means one. And that's supported by the claims themselves.

The other part of the term, active anti-tumor compound, it really is -- you have to step back for a minute and think about what does active anti-tumor compound mean? What is it doing? And it really -- what it means is the active anti-tumor properties of that compound is what gives it this anti-tumor ability. So it's the anti-tumor properties of a compound that makes it quote, active against tumors. What you'll see a lot as we walk through the specification and as we walk through the publications over and over again from the scientists, including Pharma Mar, they talk about this concept of testing these compounds. They use IC_{50} data. They use in vitro data. They use in vivo data where they test cell lines in mice and they test against carcinoma and breast cancer and all these different types of cancers. And what that is is the properties of those compounds that have activity against different cell lines. Sometimes, as Your Honor's probably very aware, there are some compounds that have activity against one type of cancer and they may not have activity against another type of cancer. But it's that testing, it's

that in vitro data, that in vivo data that you see over and over again in the intrinsic record, again in the extrinsic evidence that we cite that is -- it's the properties of that compound. Again, it's a single active anti-tumor compound. Really that compound, it's something you would put into a formulation that would be in a formulation and it possesses those properties.

Again, what I point out here too is there's no quantity requirement of this single active anti-tumor compound in these independent claims. Even if you say single active anti-tumor compound and where the active anti-tumor compound is 743, it doesn't say how much you have to have, right? It could be .1 milligrams. It could be 10 milligrams. It could be 1 milligram. The point is it's present. It's a compound. It's a thing, a noun that's present in this composition.

Now, if we turn to the specification, the patent specification overwhelmingly supports defendants' construction here. And really if you think about single compound possessing anti-tumor properties and look at ET-743, just use that as an example because I think everyone agrees that is an active anti-tumor compound and does possess these anti-tumor properties. The specification says ET-743 possesses potent antineoplastic activity. Again, it's a variety of human tumor xenografts grown in mice against these different types of cancer, cancer cell lines.

Really what that means is -- antineoplastic means that it blocks the formation of these neoplasms or growths that may become cancer. So when you're thinking about the property of this compound, ET-743, that is a property of it. It blocks the growth of this. That is, again, what gives it this anti-tumor activity in those specific -- in those mice against those specific melanoma, ovarian, and breast cancer. And just so you understand, Your Honor, human tumors, xenografts, are really taking these cells, these growths and -- from humans and grafting them, in this case, into mice. Again, it's those properties that ET-743 has that gives it this anti-tumor activity.

And I think Dr. Berkland, plaintiffs' own expert, would agree with this. In fact, when asked at deposition what makes ET-743 an active anti-tumor compound, it has been shown to have this antineoplastic activity in several cancers, and he it responded, citing to the same section of the patent specification that I just put on the previous slide, slide 16, column 2, and he says that, therefore, this claim to a lyophilized anti-tumor compound has those properties. ET-743 has antineoplastic activity and, therefore, it has those properties. That's, again, consistent with plaintiffs' -- with defendants' construction here.

The other part that I think has been missed here and was really not mentioned in plaintiffs' presentation, but I

think it's very important, is the inventors of the '557 patent and all the prior art that led up to that, they weren't only concerned with ET-743. They said their invention is applicable to other ecteinascidins or other ET compounds. And what they said specifically is those ET compounds are preferred, those other ones are preferred. For example, what you see on slide 20 here is a quote right from the patent specification: Thus, preferred compounds of this invention include. And the top left compound you see is ET-743.

But what you see on the bottom right, and you didn't hear mentioned earlier this morning, is ET-745 is, in fact, a preferred compound of this invention. It just so happened ET-743 was one of those and that's what led to the claims here. But another preferred compound that would be an active anti-tumor compound is ET-745. It's not only a compound, it's not only an active anti-tumor compound, it's a potent active anti-tumor compound that was preferred by the inventors themselves. And what you see on slide 21 is just another example from the patent specification where the inventors have that preferred compounds of the invention include these ET-745 and 770 compounds.

THE COURT: Mr. Adams, let me ask you a quick question about that, only because I'm looking at my notes from, I think, the briefing, but I could be mistaken. I thought it was in your briefing that at one point you had

mentioned that ET-745 and ET-770 were identified as particularly preferred, but when I look at the chart, ET-770 isn't there and ET-745 is identified simply as preferred, not particularly preferred. Is there an inconsistency there, or am I looking at the wrong citation? Is that in your briefing?

MR. ADAMS: I don't know that -- if we said "particularly preferred," I think that language is used in the patent and other places. If we said that, "particularly preferred," we misstated that, but I don't think we did. I think what we said was "preferred compounds." And so when these patents are written, basically -- a lot of times you have a broad disclosure. You write a bunch of stuff in there and then you start really narrowing it down to what they believe is going to be their invention. Right? In this case, when you start saying "preferred embodiments" or "preferred compounds," these are the ones you think work. Right? So to answer your question, Your Honor, if we wrote "particularly preferred," I think we were misstating that.

THE COURT: That's all right. I want to make sure. In 770, where is 770 identified?

MR. ADAMS: It's identified here on slide 21. It's the second compound.

THE COURT: Okay.

MR. ADAMS: Slide 21.

THE COURT: Got it. I'm looking at slide 20, but

it's in slide 21 that 770 is identified.

MR. ADAMS: Yeah. Your Honor, what you see is a long discussion in the background of 745 and 770, and then you keep going in the patent and you see they're narrowing it down. They don't talk about 729, but they talk about 745 and 770 as being these preferred compounds.

THE COURT: Okay. I didn't mean to interrupt. I just wanted to clarify that. I think I got it. Yep. Go ahead.

MR. ADAMS: Now, plaintiffs are arguing that defendants' construction somehow reads out these preferred embodiments of the patent, and they keep saying 22 examples and every example is read out by our construction. I think that's wrong at least for three reasons. First of all, our construction of single active anti-tumor compound, we don't believe it reads out every embodiment. In fact, our construction is really focused on the phrase "single active anti-tumor compound" and what that means given the intrinsic record. ET-743 is still present in the claim. That's an additional statement in the claim. We've never said single active anti-tumor compound doesn't cover ET-743. And that's in the examples in the patent.

And then if you look at the impurity, what plaintiffs call the main impurity, but it's the only impurity they actually tested. In every single example, all the data they

showed you, every single example was about ET-701 as the impurity. And it makes sense because that was really what this alleged invention was about is trying to minimize ET-701. And so every example has ET-743 and ET-701. And again, our construction is single active anti-tumor compound and we're not construing ET-701. That's a different limitation. And we realized that and we say that's already accounted for in the claim. That's a separate limitation. That limitation was in front of the patent examiner when this language "single active anti-tumor compound" was added. So our construction -- our construction doesn't read out those embodiments. But even if it did, even if it did, what plaintiffs ignore is the Federal Circuit case law saying there are times when preferred embodiments or other illustrative embodiments can be read out when you're construing claims. And that's because you see here in the *Helmsderfer* case that courts cannot rewrite claim language. And if so, if it results in an embodiment, one or more embodiments being read out, that's because that's the way the claims are written, not because that's the way we read it under our construction.

The other point I want to make in that is you saw a lot of slides, I think three or four slides, if I counted correctly, about ET-NF-G, this preferred formulation. Then you saw in that same slide, over and over again, a quote from column 27 of the patent that talks about ET-745. What never

happens in this patent, and what I think is not really being shown correctly, is there are no formulations or compositions shown in this patent that just show ET-745 being present as an impurity. And even if there were, even if there's language in column 27 that talks about maybe some embodiments had ET-745 present, that doesn't mean that every single embodiment, or even the preferred embodiments had ET-745 present as an impurity. Certainly, there's never any evidence that ET-NF-G, the preferred composition they keep talking about, had anything other than ET-701 and 743 present. That's the only two ET compounds that were ever talked about in the context of that formulation. If you look at the table, table 8, if you look at figure 8 and 9, those all show ET-743 purity and ET-701. That's it. Nothing more.

And then the additional point I want to make is that the claims you have cover all embodiments. Again, if there is an embodiment that has some other impurity or some other compound present there, if this construction -- defendants' correct construction is applied and there is an embodiment that is not covered, and we don't think there is, but if that were true, it doesn't matter. The Federal Circuit tells us that a claim doesn't need to cover every single embodiment. The patentee here clearly knew how to write a claim that said we have a single active anti-tumor compound. We have 743 in there and then we have this ET-701 impurity and we know how to

write the claim and we want to minimize this. That was the whole goal of the patent itself. Minimize the amount of ET-701. And that's in the claim.

So then the third reason I want to present that we're not reading out preferred embodiments, and if we are, it's not us doing it. It's really a reflection of the file history. The prosecution history here was the place. It wasn't in the claim originally. It wasn't in the specification. The prosecution history was the place single active anti-tumor compound first -- is the genesis of it, first evolved. It was in that prosecution history, you've already seen numerous times today, that that language was added. And the Federal Circuit told us we have previously explained that limitations may be construed to exclude a preferred embodiment if the prosecution history compels such a result. And that's exactly what is happening here. If any preferred embodiment, or any embodiment in this patent is being read out, and it's our position that it's not, but if it were, it's really based on that prosecution history.

And so if we go to slide 23 here, on the screen in front of you, we see the original claims. The original claim was ET composition, which comprises ET-743 and a disaccharide. As Your Honor saw earlier this morning, you know that it was rejected over the Faircloth reference. And Faircloth is a prior reference that disclosed kahalalide out. So that's an

active anti-tumor compound. It disclosed ET-743. And it disclosed them together in a composition with a disaccharide. So the examiner looked at these claims and said, well, you have one active ET-743. You have a second active kahalalide and a disaccharide. So your claim, as written, doesn't exclude that. It's part of that claim. It would be within the scope of that claim, so I'm going to reject, if you anticipate it. What I think it's important to note in that is there's no amount of ET-743 present in that Faircloth reference. It's just that it was present. ET-743 was the second one and kahalalide F is the other active anti-tumor compound that was present. So again, it was the presence of multiple active anti-tumor compounds that was the basis for this rejection.

And that rejection then led us to a claim amendment and this claim amendment was the addition of single active anti-tumor compound. And in view of that, the applicants, they made a claim amendment and then they made the argument. I think what's important to note here is that if we look at the bottom paragraph on what's slide 26 in front of Your Honor, in addition to making the amendment, the applicants argue that applicant claims would not encompass combinations of anti-tumor compounds. So they didn't say in that scope that you could have, you know, one compound that's at some level and then you can have another one. But they said

clearly would not encompass combinations of anti-tumor compounds. And the other point here is that they didn't say active anti-tumor compounds because active and anti-tumor kind of really means the same thing. If a compound isn't active, it's not going to be an anti-tumor compound if it's not active against the tumor. They know that. That's why it says active anti-tumor compound and right here is it says anti-tumor compound. They're really one in the same.

So in view of that intrinsic record, in view of the claims and the specification and in view of the prosecution history, which is clear on its face, is that this can only be limited to a single compound. We think our construction is correct that we put forth in this case.

In addition to that, if you look at the extrinsic evidence, the extrinsic evidence that defendants cite overwhelmingly supports this concept of this active anti-tumor compound having these properties, possessing these properties, these anti-tumor properties. And I don't want to go really deep into this because it gets a little bit scientific and complex in nature, but what I want to point Your Honor to is, again, this Rinehart reference we talked about 1990. The identification of these compounds, and then studying them, to understand their potent anti-tumor agents. That included 743, 745 and 770. And you'll see at the bottom an IC_{50} number versus L210. And then you see a semicolon and another test

there. What that is, Your Honor, is really testing of these compounds, that's ET-745 we've highlighted, but it's testing of these compounds to see if they have these properties of the anti-tumor activity, to see if they can inhibit the growth, to see if they are an in vitro cell test, if they are inhibitory of the cell growth, and see if they shrink tumors. Those are the properties that make these anti-tumor compounds.

Again, in 2001, again, this is before the patent was even filed, ET-770, again, has another example of being a potent cytotoxic activity testing IC data against breast cancer cells and carcinoma cells. And this theme just continues, Pharma Mar on slide 29 here, again, saying that ET-745 is a potent antiproliferative activity against a variety of tumor cells. Even more recent we see this again on ET-770. So this theme of these compounds possessing these anti-tumor properties, it was in the prior art, Pharma Mar published on it in the prior art. It goes to the background of the patent. These become preferred compounds of the patent itself. The inventors clearly knew these anti-tumor compounds had these anti-tumor properties. And, in fact, again, they said they were preferred in the context of the patent.

So that takes us to defendants' construction in view of the intrinsic record and the extrinsic evidence that overwhelmingly supports that these compounds have anti-tumor properties. Defendants' construction is single compound

possessing anti-tumor properties.

On the other hand, what we have here on slide 31 is plaintiffs' construction. Again, a single compound providing the anti-tumor activity and the composition, this is clearly a claim rewrite that really has no support in the intrinsic record.

If we go to slide 32. Again, we look at *Phillips* because *Phillips* is really the Federal Circuit telling us how to do claim construction. We look at the intrinsic record and the prosecution history. And then we can also look at the intrinsic evidence, and *Phillips* tells us, it's less reliable than the patent and its prosecution history. And generally what you see is extrinsic evidence, things like dictionaries or expert testimony or publications in the art at a relevant time. What's not listed in there -- and I think this is an important point -- is accused products, accused devices. They're not extrinsic evidence. You cannot use accused products to write in limitations. Federal Circuit has told us that many times. This concept of using over and over again, you know, as context, I think is, you know, when you do that 80 percent of the briefing and 90 percent of the exhibits, I think that's a bridge too far for context. I think it's gone to the point of writing in new limitations. And that's exactly what we see here. Plaintiffs' construction is a claim where you're rewriting by looking at the accused product.

On slide 33: Claims may not be construed with reference to the accused product. That's *Wilson Sporting Goods* from the Federal Circuit telling us that.

And then even more importantly, the accused product are processed as a form of extrinsic evidence to supply limitations for patent claim language. Yet -- that's, again, *Wilson Sporting Goods* from the Federal Circuit. Yet, in this case plaintiffs argued -- this is from the responsive brief docket 171 at 14 -- plaintiffs argued that the only extrinsic evidence relevant to this Court's claim construction analysis is Natco's representation regarding its ANDA product.

So plaintiffs are arguing that in spite of what the Federal Circuit told us, they're arguing that the only extrinsic evidence is the accused product. Again, it's not even extrinsic evidence.

So I think what comes from that is all this argument and focus, well, what's in Natco's product. Oh, that's an impurity. That can't be right. I think really when you step back here for a minute, plaintiffs have it backwards. They're improperly looking at the product until they come up with a construction. And notably, the disputed phrase "single active anti-tumor compound," it doesn't use the term "impurity" nor do any parties' construction. Plaintiffs aren't providing construction that use the word "impurity." Yet the entire discussion is about what's in our product. Right? Looking at

an infringement issue, that's for the experts down the road. That's for trial. That's not for claim construction. And whether or not ET-745 or 770 are, quote, anti-tumor compounds is not really a question for claim construction. The patent says they are. The inventors believe they are. In fact, they were preferred compounds of the invention. The prior overwhelmingly says they are, but that doesn't really -- isn't really part of the claim construction inquiry. The claim construction inquiry is about what is the term "single active anti-tumor compound," not what's in Natco's product.

So again, I think if you go to slide 36 here, Your Honor, again, you've see this slide before, but it's -- it's really highlighting the fact that ET-745 is a preferred compound at the invention.

So I think where that takes us to, Your Honor, is really this major focus on our product, first of all, is wrong. We pointed that out in our reply brief, and what I show on [redacted] We have other ones. [redacted]

You heard some testimony and discussion about Dr. Reddy, one of Natco's fact witnesses. Dr. Reddy worked on the development of the drug substance. So, you know, how do you make a drug substance? He worked on that. He understood that

development process and the impurities and the compounds present in that process and he testified to that. In fact, he [redacted] that was not put into plaintiffs' responsive brief. That was left out. That directly contradicts their position. The data that's on top of slide 37, again, directly contradicts their infringement position.

But again, that's evidence relevant to infringement. That's not claim construction extrinsic evidence. And the fact that the patent describes ET-743, 745 and 770 as these active anti-tumor compounds, these two facts in front of plaintiffs caused them to go out and rewrite the claim. So again, what we show here on slide 38 is taking the language of single active anti-tumor compound, shuffling it up, and then adding some more information there that really does a lot of damage to the claim itself, but with the goal of trying to cover the accused product.

So you'll see "a single" is still there but "compound" is moved around. There's the words "providing the," has no support in the intrinsic record. Not even sure what it means. "Anti-tumor" is left, but then "active" is changed to "activity." And then there's "of the composition." I'll walk through why there's problems here in a minute. But again, this is a complete claim rewrite in view of the accused

product, which the Federal Circuit again and again has told us is improper.

So what this does, Your Honor, is in terms of functional requirement of this thing, this active anti-tumor compound, it now needs to provide something, provides the activity of the composition. And what "of the composition" is I'm not entirely sure, but that's what they say it does.

They also rely upon conclusory expert declaration to report a requirement that impurities cannot be active anti-tumor compounds. And then by rewriting the claim here they broaden the claim to allow "single" to encompass multiple compounds identified by the patent as active anti-tumor compounds. Those include 745, 770 and others.

So that's -- before I get to slide 40 here, that's the whole idea, the goal of their construction. To take the accused product, rewrite the claims, and then try to cover the product based on that.

Plaintiffs also rely upon -- heavily rely upon other relevant extrinsic evidence. And the Federal Circuit, as shown on slide 40 here, is telling us over and over again it may be useful to the court, but it's unlikely to result in a reliable interpretation of the claims scope unless considered in the context of the extrinsic evidence.

And then the *C.R. Bard* case for the Federal Circuit 2004: Extrinsic evidence is generally less significant than

the intrinsic record in determining the legally operative meaning of the disputed claim language.

So slide 41 is just a long listing. It's essentially a laundry list of all the times that plaintiffs are relying upon. What I've quoted here is extrinsic evidence because it does include a lot of our accused product, which is not even extrinsic evidence but there's very little substance when you get to their arguments on extrinsic record. Really they're trying to look at the accused product over and over again or other extrinsic evidence to get into their claim rewrite.

And then the *Ruckus Wireless*, the Federal Circuit tells us that legal error arises when a court relies upon extrinsic evidence that contradicts intrinsic record. And that's exactly what you see here and what plaintiffs are doing. Their extrinsic evidence does, in fact, contradict the intrinsic record.

Now let's talk about their extrinsic evidence. One of those pieces of extrinsic evidence is their expert declaration of Dr. Berkland. Now plaintiffs have now admitted that their expert declaration is irrelevant to claim construction. They state in their responsive brief that the only extrinsic evidence relevant to this Court's claim construction is analysis of Natco's representations regarding its ANDA product. By default, by admission, they're saying their expert declaration is at fault. We agree with that. We don't

think their expert declaration is relevant to claim construction for several reasons.

As you see here on slide 44, in the *SkinMedica* case, this is a pretty important case when it comes to expert testimony. The Federal Circuit told us in 2013, expert testimony, in particular, is less reliable because it's generated at the time of and for the purpose of litigation and thus can suffer from bias that's not present in the intrinsic record. For that reason, conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court. That's *SkinMedica* Federal Circuit 2013.

And that's exactly what we have here. In addition to plaintiffs saying their own declaration isn't relevant to claim construction, we don't think it is either. Dr. Berkland's declaration was written a few months ago, October 2021. The patent was filed 15 years before, 2004. The declaration is very conclusory. It really cites -- has very few cites. It doesn't cite other publications for the time about they might think or know. It just reaches a conclusion and ultimately the declaration just parrots plaintiffs' opening *Markman* brief. It has the same irrelevant extrinsic evidence that plaintiffs relied upon. It's uses that accused product to rewrite the disputed claim term here.

Now the other piece of extrinsic evidence that plaintiffs rely upon is, and I say extrinsic evidence --

THE COURT: I want to make sure, Mr. Adams. Your argument is that the plaintiffs have a declaration of their expert, but then they're also admitting their expert declaration is irrelevant?

MR. ADAMS: That's right, Your Honor.

THE COURT: Is that solely because of the language that you cited to in their brief? I mean, look, I'm going to ask Ms. Royzman on rebuttal whether she agrees with that. Is that a practical position you want to take, that they decided their expert's irrelevant?

MR. ADAMS: That's what they said. I certainly didn't write their responsive brief or don't know what their intent was, but that's what they said. Our position is that it is irrelevant for the reasons I just talked about on slide 44.

THE COURT: All right. I'll ask her about it. But okay.

MR. ADAMS: Plaintiffs have a discussion, they rely upon Dr. Reddy's testimony. Again, that's -- that's really not even extrinsic evidence, again, for claim construction because it's not -- it's accused product they're really talking about. You know, in the discussion before we filed our reply brief plaintiffs admit that they're not relying upon testimony of Dr. Reddy for purposes of claim construction. Not to mention, as we point out in our reply, they're really

taken out of context. It's limited to a single table. We've shown other data that they're actually -- just, they're wrong on what is or isn't in the ANDA. But at the end of the day, it doesn't matter for claim construction. The point is that it's, again, looking at the accused product and not real extrinsic evidence or the intrinsic record.

So for all those reasons, we don't think any of this extrinsic evidence really supports plaintiffs' construction.

Now if you turn to the intrinsic record, I think in some ways things get even worse when you start looking at the claims themselves, when you start looking at the patent specification and the file history to try to find support for plaintiffs' construction.

Let's start with the claims as we do under *Phillips*. Plaintiffs make the argument that they're rewriting -- that they're construing the term "single active anti-tumor compound" and it has support in the claims, but what they're doing is rewriting the claims. So to say they have support and then they rewrite it just doesn't -- is sort of circular. But what happens when they rewrite the claims is they change the dispute phrase from a noun to a verb and add some functional requirement not found in the claims. And then the terms used in plaintiffs' claim construction is also not found in the claims elsewhere. And then ultimately what happens with this claim rewrite is it raises more questions than it

really answers.

So if we look at slide 48 here, "a single active anti-tumor compound" rewritten to the single compound providing the anti-tumor activity of the composition. The Federal Circuit has told us the claims -- the courts must construe the claim as written, not as patentees wish they had written it. And that's exactly what they're doing here is rewriting the claims.

So what I want to focus on now a little bit is what we really are left with after construction. The disputed phrase is really -- it's a thing that you would place into a recipe back in the kitchen, Your Honor. It's a formulation or composition with something you put in there. Just like the disaccharide is something you put in there. The active anti-tumor compound is something you put in there. It's a thing. A compound, you know, an active anti-tumor compound. Plaintiffs' construction turned this thing, or noun, on to its head. They turned this phrase into a verb. It's providing the active -- the anti-tumor activity of the composition so it's got to do something now with the function. So they turn the noun, which is a thing, into a functional verb. It has to do something.

And then in doing so, it really raises more questions than it answers. This concept of providing -- they don't explain what providing means. Providing to whom or to what?

Again, this isn't a method of treatment. This isn't even limited to humans. I mean, this is a composition that you go make in your lab and that's it. It really -- providing doesn't -- no one knows what that means. It doesn't give any context, to whom or to why or how is it providing. Plaintiffs also don't explain why they change "active" to "activity" other than it changes from a noun to a verb.

And then the last part "of the composition" really has no support anywhere. "Of the composition." There are numerous times throughout their briefing they'd say provide the activity to the composition. Their construction says "of the composition." Again, this has no support in the claim or the intrinsic record at all, and it really raises a lot of questions. What if there were a second compound? How do you determine if it is providing "of the composition"? And that's a question that no one can really answer.

So when you move on from the claims specification of the '557 patent, things don't really get any better for plaintiffs' construction. The phrase itself, a single compound providing the anti-tumor activity, "the composition," that's not found in the specification. The word "providing" is not used in specification regarding this disputed term, "single active anti-tumor compound." Plaintiffs' functional claim requirement that's now been included in, again, that's not in the specification. There's no guidance as to what that

means, how it provides, how much is required to provide. Provide to whom or to what? And then there's a discussion of single active anti-tumor compound being active pharmaceutical ingredient or API.

One of the questions Your Honor asked earlier about the labeling of a product to Mr. Williams was a regulatory question. There's a lot of regulatory questions that are involved. That's not a patent question. That's a regulatory question of what the FDA may do. Same thing with how do you characterize what's in your product? You have to tell the FDA based on a big book of regulations what's our product? How much is in there? There are times when the FDA doesn't even require you to identify it. It's at a certain level. So there may be regulatory questions, but those regulatory questions are not what's in the patent. The patent describes a composition of formulation. An active pharmaceutical ingredient is very different than single active anti-tumor compound is used in this patent. Again, that API is a regulatory term. This is not API used in a treatment claim. Again, it's not even limited to humans. This claim you just made in the lab. So when we look at that specification, the specification doesn't support plaintiffs' new construction.

And then finally we look at the prosecution history, Your Honor, and we've seen this several times today, but the single active anti-tumor compound, single means single. And I

think, you know, there's an argument that, oh, well, we only meant to limit to this. But single means single. It can't mean something more. And the Federal Circuit has told us in the *Norian Corp* case in 2005, in such cases we have held patentees to the scope of what they ultimately claim, we have not allowed them to assert that claim should be interpreted as if they had surrendered only what they had to. So whatever their intent is now, single must be single, not one plus another one.

Again, that was clear from the language that was used by the applicants themselves. On slide 54, applicants' claims would not encompass combinations of anti-tumor compounds.

So even in view of that intrinsic record, even in view of the prosecution history, plaintiffs rewrite the claim, as we see on slide 55, but in application it goes even further because the language "single" when you apply plaintiffs' construction of providing the anti-tumor activity of the composition, they actually really don't even mean single, Your Honor. Even though they say "single" they don't mean it. And why I say that is plaintiffs contend that under their construction, even if there are multiple active anti-tumor compounds in there, the one that is providing the activity to the composition or of the composition is the single active ones. So if you have several, it really doesn't matter. What they say is -- under the construction is that there must be

one that provides the anti-tumor activity of the composition. And this really played out in the deposition of plaintiffs' expert, Dr. Berkland. Now, he was asked to determine whether a lyophilized composition with a one-to-one ratio. So you took, you know, 50% of ET-745 and 50% of ET-743, which you had two active anti-tumor compounds. Right? Under the construction he doesn't know. He doesn't know. So I think that's very telling that their construction of providing the anti-tumor activity composition can't be right because, again, it's reading out the language of "single."

So really what this leaves us with is a very ambiguous term. The parties agree to address the definition down the road, but what you see from this new claim rewrite is that no one really understands what it means. Under plain meaning one and only one is single. Under plaintiffs' construction one plus any number of additional active anti-tumor compound, as long as they do not provide the anti-tumor activity of composition, or they're called impurities. And again, through deposition of Dr. Berkland, we asked him questions about how one could determine whether a compound, such as ET-745, is an active anti-tumor compound such that it's providing these anti-tumor activity of the composition. He couldn't answer the question. I think that question is too broad to answer. It relies upon a bunch of things. The type of cancer being treated, what's being measured. The type of cancer being

treated is irrelevant and immaterial to the claim in front of us. It's not a treatment claim. And so ultimately even Dr. Berkland can't figure out how you apply this without reading out the single limitation.

And then there's an argument that ET-701 is an impurity and so somehow under defendants' construction that we are -- are wrong because ET-701 is an impurity and we somehow read that out. Again, I mentioned this earlier today, that's certainly not true. ET-701 is a different limitation in the claim that's dealt with separately. And that's an impurity that the patentees knew about, they tested it, and that was part of the bargain with the patent office to get these claims.

But if you buy into their impurity argument and you try to understand their construction and how do you apply it, again, a deposition from Dr. Berkland sort of solidifies defendants' position, which is he could not answer whether you take ET-745, present at 10%, whether that would be an impurity. Is that a second single active anti-tumor compound? Is that an impurity? You know, what about 20%? 50%? Is it -- at what level does it start providing the anti-tumor activity to the composition? It's certainly not clear from the claims. It's not clear from the specification or plaintiffs' construction. And Dr. Berkland didn't know either.

And so what that really does is say that if their construction is applied, it imports a bunch of ambiguity and also later down that road that would require that these claims are held invalid because they're indefinite. And the Federal Circuit has told us that claims are invalid for indefiniteness where a person of skill in the art could not determine the bounds of claims. And that's exactly what you see here with plaintiffs' construction. And Dr. Berkland, their own expert, couldn't really understand that.

So, Your Honor, that's all I have on my initial presentation, unless you have questions.

THE COURT: No. Thank you, Mr. Adams. That was helpful.

Let me ask you guys this, though, before I break, and will keep my word that we will take a ten-minute break before hearing from Ms. Royzman on a reply or rebuttal. Are we marking these decks as exhibits to this hearing? Have you guys discussed that and what were you proposing I do with these?

MR. ADAMS: We did discuss that, Your Honor. My position would be these are demonstratives, not exhibits to the claim construction briefing. The exhibits were obviously submitted as declarations.

MS. ROYZMAN: We're fine either way, Your Honor.

THE COURT: Okay. I mean, there's no objection. So

you're not looking necessarily for me to mark these or identify them as exhibits or attach them or anything like that.

MS. ROYZMAN: No.

THE COURT: Okay. All right. Why don't I keep to my word. You guys want to break for ten minutes and then just kind of jump back on? I'll probably just stay on. I'll just mute and knock out my video and take a break. But does that work, Ms. Royzman, for you?

MS. ROYZMAN: Yes. Would 15 minutes be okay, Your Honor, just for --

THE COURT: Absolutely fine. You tell me.

MS. ROYZMAN: That would be helpful.

THE COURT: It's a little after one. So we'll come back a few minutes after quarter after.

MS. ROYZMAN: That's perfect. Thank you, Your Honor.

THE COURT: I'll see you guys in a bit.

MR. ADAMS: Thank you.

(A short recess occurred.)

THE COURT: We're back on record. I have two quick questions, but do you guys want to do this rebuttal first? Even though it better be quick, but I'll give you guys a few minutes to say your peace, but I had two quick questions.

Ms. Royzman, what's your preference? I don't want to cut off your flow if you're ready to give Mr. Adams a punch.

MS. ROYZMAN: Your Honor, I'm happy to address your questions first.

THE COURT: Here's my first question, and I'll tell you, both are tailored to making you guys do as much work as you need to and me do less. Here's my first question. My understanding is that the construction that I'm being asked to apply, it's single active anti-tumor compound, right? It's a single active anti-tumor compound. My question is, can the parties agree on what "single" means? Meaning can I reduce the term to active anti-tumor compounds? Or are you guys even disputing what "a single" would mean within that term? Do you understand my question? I'm trying to figure out whether we can reduce the actual term to active anti-tumor compound because both plaintiff and defendants are in agreement on what the word "a" and "single" mean.

Do you have a response to that, Ms. Royzman? I just want to get your sense of it. If your answer is you guys are fighting over "single," then I'll back off, but I'm trying to reduce what I need to look at.

MS. ROYZMAN: Yeah. I think, Your Honor, I mean, I think it's important for, you know, for the context, but I don't think there's a dispute with respect to -- I think that phrase is important, but I don't think there's a dispute as to the meaning of "a" or "single." And I think one of my slides had reflected that.

And so I think that's fair, but I think the phrase is -- the overall phrase is important and probably should stay as is, but I don't think Your Honor has to construe "a single" because there's no dispute as to -- as to that meaning whatsoever.

THE COURT: Mr. Adams, what's your take? Are you disputing that? I don't mind keeping that in, but are you disputing what "a single" would mean with respect to plaintiffs? It doesn't sound like they're fighting over it, but I don't know.

MR. ADAMS: Your Honor, I don't think we dispute what "a single" means. I think it means one. I think the phrase as a whole was added during the prosecution as a phrase, single anti-tumor compound. So I think that phrase as a whole has a specific meaning in the context of the entire intrinsic record. So I think that's why the parties brought that up originally for construction. So I think in view of that, even though we don't dispute what "single" means, we think single means one, I think the phrase as a whole, it's really the crux of the issue.

THE COURT: I will tell you what. Based on both your responses, which I think are consistent with each other, so it sounds like you're in agreement, I'm not looking to cut out "a single," but at the same time on the record it's my understanding that you're not actually disputing, though, the

meaning of the term "single," but you'd like to keep it within the term for purposes of construction, correct?

MS. ROYZMAN: That's correct, Your Honor.

THE COURT: Let me switch to a second question. This has to deal with extrinsic evidence, and I will again pose this question to both of you. Look, my experience in a *Markman* is limited based on my past life and even now as my recent elevation, but I've seen this before with other district judges so I thought I might as well propose it here and get a sense from at least the parties in this specific case when I need to delve into extrinsic evidence.

Say, for example, I agree with plaintiffs that the plain and ordinary meaning apply and no construction is necessary. In that content, would I still need to delve outside of the claim, the specification, the prosecutorial history, and delve into extrinsic evidence, or would that not be necessary? Or if it doesn't matter what I do in this case, I have to delve into that? This is, again, just how much work do I need to do and how many different sources do I have to analyze?

MS. ROYZMAN: I think Your Honor could resolve this claim construction dispute based on the intrinsic evidence. And so I don't think you need to delve into it other than to the extent Your Honor finds it helpful. And, you know, so the expert declaration talks about impurities and it discusses --

part of the reason it doesn't have a whole variety of other citations is because it really discusses the intrinsic evidence. But Your Honor could decide the claim construction issue just based on the -- on the intrinsic evidence, and courts often do.

THE COURT: Mr. Adams, where are you on that?

MR. ADAMS: My position is shockingly similar to Ms. Royzman's. I agree the intrinsic record. You can get into the construction here based on the intrinsic record alone. I don't think you have to go to any of the extrinsic evidence that's in front of Your Honor.

THE COURT: All right. Is that something I can -- so if I do this analysis and I deal simply with the intrinsic evidence, the claim specification, the prosecutorial history, do I have the parties' agreement that I don't need to delve into intrinsic evidence for purposes of resolving this dispute? Because that's what I'm going to put no matter which way I go. I am just trying to figure out whether it's necessary for either side. I'm not so sure it benefits either of you, and I don't think anyone's prejudiced, but I want to make sure that we're clear on the record.

MR. ADAMS: You certainly have the defendants' agreement to that, Your Honor.

THE COURT: Ms. Royzman?

MS. ROYZMAN: Your Honor, and you have ours. I

think, you know, it should only be consulted to the extent it's helpful to Your Honor. That was the intent of it.

THE COURT: All right. I appreciate that from both of you.

Those were my only two questions. Like I said, I'll keep the term the way you guys have provided it as "a single active anti-tumor compound." That's the term before me, so I won't be reducing it, but my understanding is the term "a single" is not actually in dispute, at least the meaning of that word is not in dispute. My other understanding is that I will move forward, and regardless of my analysis, I will be reviewing intrinsic evidence only, which is in agreement by the parties; that I do not need to delve into extrinsic evidence unless the Court deemed that it might be helpful to me.

That being said, Ms. Royzman, I appreciate it. I'm sorry for the delay. How much time are we looking at here? Because I know Mr. Adams is going to want to have his last word, and I don't want to go back and forth. How long are we doing this?

MS. ROYZMAN: I think it should be fairly, fairly quick; maybe ten minutes or so.

THE COURT: All right.

Mr. Adams, I'll allot you around the same amount of time. Let's keep it fairly tight.

Ms. Royzman, I'm happy to hear from you in response to Mr. Adams' presentation. You've got the Court's attention.

MS. ROYZMAN: Thank you, Your Honor.

So Mr. Adams started with the local rules, and again, we find that surprising, but there are obviously no violations of the local rules. Judge Goodman considered that and rejected defendants' arguments. There was back-and-forth. The back-and-forth resolved a lot of the claim construction disputes. The parties better understood each other's positions. We elaborated on our ordinary and plain meaning in view of our, you know, at that point full understanding of what defendants intended with their construction, which is very hard to -- very hard to understand so that's on the local rules. There's no rewrite of any kind.

Then slide 37 that was put up by Mr. Adams, this was a slide or an image from the reply brief that that's -- that's incorrect and out of context from start to finish, and we tried to provide that context in our proposed reply brief, which is DI-181.

Now I'd like to pull up columns 7 and 8 of the patent. Dan Williams will help with that. He's got much better technical skills.

And so I think, Your Honor -- because defendants' briefing did describe ET-745 and ET-770 as "particularly preferred" in their brief, that surprised us, and Your Honor

asked a question about it. And what column 7 and 8 made clear is there's a list of preferred compounds, and ET-743 is listed first. The one other one, I guess, that's at issue here is ET-745, and it's described as "preferred" here. And then it states -- and here's where the "particularly preferred" language comes from -- it's right here immediately below ET-743, also known as ET-743 or ecteinascidin. 743 particularly preferred.

And then the specification continues to focus on ET-743 because those are really the formulations that are at issue in the claims and at issue here. We are not dealing with ET-745 compositions or ET-770 or any other ET compound. And so we have a summary of that.

Dan, could you pull that up? Sorry, Dan. Maybe slide 2, ET-743 formulations.

In the context of the claimed invention, in the context of the claims, ET-745 and ET-770 simply are not actives. ET-743 is the particularly preferred compound of the invention. That's in column 8, what we just looked at. All of the examples are ET-743 formulations. There are no ET-745 or ET-770 embodiments or examples. There's no formulation where either compound is the active compound. There are no claims with ET-745 or ET-770 as an active compound. These are potential impurities of ET-743 formulations, ie., formulations where ET-743 is the active compound. These are only

impurities in the context of the claimed invention, which is really all that's relevant here.

Can we go back to the patent, Dan. Could you pull up column 27.

Your Honor, and so here, in column 27, it's -- one, it's made very clear that formulation ET-NF-G is a preferred formulation. That's the ET-743 formulation that's described this way.

And then immediately below, contrary to statements from Natco from Mr. Adams about testing, or whatever, it's very clear, embodiments of formulation, according to this invention, were tested after storage under a plurality of conditions, and total impurities, including potential ET-701 and potential ET-745 and potential other ET compounds, other compounds did not exceed a certain percentage after nine months. That's just made very clear.

So this is not just about ET-701. The patent is clear that there are potentially a whole variety of impurities, and they have been reduced by the unique formulation that the defendant -- that the plaintiffs came up with -- that the inventors came up with.

And if you look at the claims, all of the claims are to, again, ET-743 formulations. They are not formulations of other things, and they reference the main impurity. Okay.

So Natco's construction, and Mr. Adams talked about

this, he said, well, maybe, you know, maybe it excludes some embodiments, but that's okay. ET-NF-G is a preferred formulation, and the construction proposed by defendants and their theory as to its meaning wouldn't just read out ET-NF-G, which actually is specifically claimed in claim 15, if Your Honor can see in claim 15, you have the exact amounts. And so I don't know what Mr. Adams was talking about when he said the claims don't provide particular amounts. Some of the claims don't recite amounts, others do. But it's very clear that the proposed construction and defendants' theory would turn the patent into a complete nullity. It would read every embodiment out of every claim, including the embodiment that Natco and Sun copied exactly.

Now, Mr. Adams made a number of critical admissions during his presentation that I'd like to flag for Your Honor. First, he said the claims are narrowly drafted, and we agree. The claims are narrowly drafted. They are to ET-743 compositions. They're not to other compositions. And ET-743 compositions, as immediately stated above the claims, can have certain impurities.

He also admitted -- and I'd like to pull up our slide crossing out "active." But he admitted quite expressly that the construction that's proposed by defendants reads out "active" because it does. Because they're equating a single active anti-tumor compound with anti-tumor compound. It's

just wrong. It's clear error. It's an admission of clear error.

And then he also admitted that the active anti-tumor component, the active anti-tumor compound is the thing you put into the formulation. Well, we agree. It is the thing that you put into the formulation. It's the active. It's ET-743. And the inevitable potential impurities result from that active, not separately. The only active that's put into the composition is ET-743. And plaintiffs' construction, the alternative construction or elaboration on the plain and ordinary meaning isn't functional, isn't doing anything functional. It's a thing. An active is a thing that provides anti-tumor activity. That's what it does. Here we have an anti-tumor composition, and the addition of "composition" was highly important and joins issue because defendants have stripped possessing properties from the composition. And they have to because they're relying on the alleged impurities in support of their non-infringement position. That's -- that's what they're doing and that's -- that's the -- that's the explanation.

So I think that's largely it, Your Honor. We are -- the case law makes clear that it's important for the Court to understand the dispute and that the accused product and defendants' infringement theories are critical to understanding that dispute. And plaintiffs are not relying on

the accused device to supply any claim limitations. They are using the accused device to provide an understanding of the actual dispute. And that's -- that's all that's -- that's all that's happened here, and they think that's -- that's essential.

So in -- in sum, the Court should adopt the ordinary meaning based on the intrinsic evidence or the construction that that's -- that's proposed by plaintiffs, which just elaborates on the ordinary -- on that ordinary meaning of what "an active" is, what an active anti-tumor compound is in the context of that claim.

Thank you, Your Honor.

THE COURT: Sorry. Thank you. I was on mute.

Mr. Adams, do you want a few minutes?

MR. ADAMS: I do. Thank you, Your Honor. I'll be really brief here.

I want to first start with -- I think it was the question you asked about "preferred," "particularly preferred" in our briefing and rebuttal to Ms. Royzman.

If I can share my screen here, I have traced that back to the patent. So it is there. I wasn't wrong. But let me just share this screen here. If we go to column 7 -- give me a second to get there. If we go to column 7, lines 4 and 5, this is where that language comes from. Compounds following formula 3 are particularly preferred. It's a generic compound

here and it has different R groups. Those R groups are attached. Here is one, R-21. This is what leads us to ET-745 and ET-770. So I think our language "particularly preferred" with a compound is actually correct and supported by column 7, lines 4 and 5, of the patent.

The next point I want to make is really Ms. Royzman talked about column 27 and how somehow we were reading out this -- this -- the preferred embodiment of ET-NF-G, and as I understand the argument, I think what she's saying is ET -- EFT(sic) has impurities of something more than ET-701, and that's simply not true.

If we go the data in the patent, again, all the data that's presented in the patent for ET-NF-G -- sorry for the scrolling, Your Honor. Let me get to it. The data is right here. Look at this table. The table in front of you, Your Honor. This is formulation ET-NF-G, has impurity -- and I'm looking at column 27 here around line 20 through 25. ET-NF-G has purity data. It goes up to three months. There's no ET-701 data here. There's no ET-745 or some other ET compound data other than ET-743. So this concept that ET-NF-G is somehow read out by our construction, that is simply just not true. There's no data of ET-745 present. And the language that kept coming up over and over, it comes from column 27 around line 37. Embodiments of formulations according to this invention were tested.

It doesn't say -- it goes on to mention ET-745 here. That's the only time ET-745 is mentioned in this patent other than to talk about it as a preferred compound of the invention. It shows it one time here. But this section doesn't show any data of any specific formulation. Certainly not ET-NF-G. And it doesn't say every embodiment, preferred embodiments. It simply says embodiments of formulations according to the invention. And that claim is -- you know, patentees use when they're talking about something they did here. It's not saying every single thing we tested had this ET-745. It's simply saying that we tested some. These were tested out at nine months.

If we look at column 27, line 46 here, I've highlighted on the screen. This is nine months. The claims talk about three months, claim 1, claim 22. This isn't even within the scope of the claim. The claim is at three months. This data it's talking about is not of every formulation. It doesn't even tell us what the data is for ET-745. It's not about the preferred embodiment of the claim because ET-745 isn't mentioned in the claim. It's also at nine months. It's nothing to do with the claims at three months. At best, it's a different embodiment that's even claimed in any of the claims because it's at nine months.

So the argument used in this information right here on ET-NF-G, the argument we're somehow reading out embodiments or

preferred embodiments, is simply not true.

Now, the next point I want to make is -- I just heard I made some admissions. I obviously disagree with those. I think one of the arguments is that we admitted that we were reading out the word "active." Again, that's simply not true. I think we said over and over again that we construed the claim term, "active anti-tumor compound," we construed that to possessing anti-tumor properties. We're providing those construction words. We're not reading out the word "active."

Then the last point I want to make is the -- you heard a discussion there at the end about the accused embodiments. I thought we just agreed we're not going to have Your Honor rely on intrinsic evidence, so I will say none of that is relevant. It's, again, not intrinsic evidence. It's the accused product.

But no matter how you slice this, at the end of the day, these claims require single active anti-tumor compound. The whole alleged invention was about minimizing the impurity ET-701. Yet under plaintiffs' construction with single active anti-tumor compound allowing other things like ET-745, 770, or who knows what else, it just doesn't make sense that you can -- you need to limit ET-701 to less than 2%, that's what the claim requires, what this whole idea was about. Yet under the construction of providing, you can have any amount of what they call impurities. You can have 20% of ET-745 under their

construction and it still would be covered by single active anti-tumor compound under their construction. That simply cannot be correct.

So regardless of what's in our product, regardless of that analysis of the accused product, plaintiffs' construction cannot be correct based on that simple principle that it requires single active anti-tumor compound.

That's all I have, Your Honor.

THE COURT: All right. Well, thank you, Mr. Adams.

I don't know if we can take off the document or not, although I don't know if we need it.

First of all, thank you, counsel, Ms. Royzman and Mr. Adams, and I think Mr. Williams also. I know he presented on the technology early on, so I want to thank him for his presentation. I can see Charlie Lizza and Bill Baton sitting patiently waiting for me to get to my lunch or sign off.

I'll take your tutorial under advisement. I've got all the briefs, so I think the issue is now back in my lap.

Is there anything more that we need to discuss, Ms. Royzman? From the plaintiffs' perspective, is there anything additional that we need to talk about today, whether related to this claim or not, while I have you on? Otherwise, I'm going to go to Mr. Adams and I'm going to adjourn for the day, but anything from plaintiff?

MS. ROYZMAN: No. Thank you, Your Honor. Thank you

for your attention.

THE COURT: Thank you for your time.

Mr. Adams, anything on your end that we need to address? Otherwise, the issue is with me.

MR. ADAMS: Nothing else from defendants, Your Honor. Thank you for your time.

THE COURT: What about your codefendant? Somebody is on here. Mr. Miller, anything on your end?

MR. RICHTER: Your Honor, I think that's us, and I don't believe so, no.

THE COURT: Everybody, I hope you had a wonderful New Year's. I've got some work to do this on this case ahead of me, so let me let you all go. It was nice seeing all of you and hopefully at some point later in 2022 we'll be doing this in person, but for now this is the new world order over here. So nice seeing everybody. Be safe. Take care.

MS. ROYZMAN: Thank you, Your Honor.

MR. ADAMS: Thank you, Your Honor.

(Court concludes at 1:47 p.m.)

FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE.

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I certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

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/S/ Megan McKay-Soule, RMR, CRR **January 11, 2022**

Court Reporter Date

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